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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/707,135	11/21/2003	Osvaldo Antonio Tiberio		1134

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EXAMINER

GIBSON, KESHIA L

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 08/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.



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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

Office Action Summary	Application No.	Applicant(s)	
	10/707,135	TIBERIO, OSVALDO. ANTONIO	
	Examiner	Art Unit	
	Keshia Gibson	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 7-9, 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 10, 11 and 14-20 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Oath/Declaration

1. It was not executed in accordance with either 37 CFR 1.66 or 1.68.

The oath/declaration has not been signed properly. See 37 CFR 1.4(d) for permitted signatures. A new oath/declaration is required.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "internal portion" and the "external portion" of the tube as well as the plastic membrane being inserted 1 cm from the inner end of the tube must be shown or the feature(s) canceled from the claim(s). (The applicant needs to label those portions of the tube that are being considered the "internal portion" and the "external portion" of the tube for clarification purposes.) No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

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of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that

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the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

5. The abstract of the disclosure is objected to because it exceeds the 150-word limit, contains implied language, requires some corrections in punctuation, and makes reference to claims. Correction is required. See MPEP § 608.01(b).

6. The use of the trademark "Thin-Prep" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

7. The disclosure is objected to because of the following informalities: 1) the use of commas to denote measurements having decimal places should be changed to the use of a period (i.e., "1,5" cm should instead read "1.5 cm") (this occurs throughout the specification and claims; 2) multiple punctuation problems exists throughout the specification, including that between paragraphs [0028] and [0029]; and 3) it is suggested the paragraphs [0022]-[0023] and [0025] be removed from the "Brief

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Description of Drawings” section and be placed in the “Detailed Description” section or removed from the disclosure all together. Appropriate correction is required.

8. The disclosure is objected to because of the following informalities: it is unclear whether the use of the “per” in such language as “14 cm long per 1 cm wide” is to mean “for every” or “by” because using the former interpretation, a tube that is 28 cm by 2 cm would still meet such a limitation. The use of such language occurs throughout the specification and the claims. For purposes of examination it has been assumed that the applicant intended for the term “per” to be analogous to the term “by.” Appropriate correction is required.

Claim Objections

9. Claims 7-9 and 12-13 are not in proper dependency. These claims are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 7-9 and 12-13 have not been further treated on the merits,

10. Claims 4, 6 and 10 are objected to because of the following informalities: “said extra-thin plastic membrane” (claim 4), “the inner end of the tube” (claim 4), “its central part” (claim 4), “the tube’s edges” (claim 4), “the internal side of the tube” (claim 6), and “its proximal end” (claim 10) all lack proper antecedent basis. The following corrections

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are suggested: "said extra-thin plastic membrane" changes to "an extra-thin plastic membrane"; "the inner end of the tube" changes to "an inner end of the tube"; "its central part" changes to "a central part"; "the tube's edges" changed to "edges of the tube"; "the internal side of the tube" changes to "an internal side of the tube"; and "its proximal end" be changed to "a proximal end." Also see MPEP 2173.05. Appropriate correction is required.

11. Claim 6 is objected to because of the following informalities: the "as claimed in claim 1" in line 3 requires correction; it is assumed that the language was intended to read "as claimed in claim 1). Appropriate correction is required.

12. Claims 3-4, 6, 11 are objected to because of the following informalities: the use of the language "(as claimed in claim 1)" and all other similar language that occurs after each claim's preamble is considered improper and should be removed. Such language as "Apparatus as claimed in claim 1," which serves as a preamble is appropriate. For purposes of this Office Action, a claim is considered to depend as stated in the preamble of that claim. Appropriate correction is required.

13. Claim 4 is objected to because of the following informalities: the use of "however" is objected to and removal is suggested. Appropriate correction is required.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

16. Claim 3 recites the limitation "the brush" in line 4. There is insufficient antecedent basis for this limitation in the claim. Although applicant follows the reference to the brush with the language "(as claimed in claim 6)," such reference is also improper because Claim 3 depends from Claim 1, not Claim 6. Furthermore, if the claim were to be dependent from Claim 6, then it is objected to because it precedes the claim from which it depends. Appropriate correction is required.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Leet et al. (US 6,036,658).

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In regard to Claim 1, Leet et al. disclose an apparatus 10 for collection of cervical tissue comprising a cylindrical plastic tube 11 and a cylindrical plastic stick 22 (Figs. 1-2, 7-8; column 2, lines 1-28).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

21. Claims 2, 5-6, 10-11, and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leet et al.

In regard to Claims 2 and 5, as discussed for Claim 1, Leet et al. disclose that the apparatus 10 comprises a tube 11 that widens at a particular point along its length; the stick comprises an internal portion and an external portion (Figs. 1-2, 7-8; column 2, lines 1-16). Leet et al. do not expressly disclose that the tube 11 or stick 22 have particular length and width dimensions. However, the apparatus is to be inserted into

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the vagina in order to collect samples from the cervix. As such, the tube and stick would have to be of a suitable width to be insertable into the vagina cavity and would have to be long enough to extend through the vagina and reach the cervix. Therefore, the width and length of the tube and stick would affect the ability of the device to be inserted into the vagina and reach the cervix for sampling. It would have been an obvious matter of design choice to a person of ordinary skill in the art to provide the tube and stick of Leet et al. with the widths and lengths specified by the claimed invention since the claimed invention has not disclosed that doing so provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the claimed invention to perform equally as with Leet et al. because both inventions are sampling devices comprising cylindrical tubes having stick brushes within them and designed to be inserted into the vagina for collection of cervical tissue.

Furthermore, it would have been obvious to one of ordinary skill in the art to provide the tube and stick of Leet et al. with the widths and lengths specified by the claimed invention, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

In regard to Claim 6, the internal portion of the stick 11 has an enlargement 30 and comprises a nylon brush 26 (Figs. 1-9; column 2, lines 29-48).

In regard to Claim 10, the external portion of the stick 11 has an enlarged part 24 which is capable of serving as a stop (Figs. 1-2, 7-8; column 2, lines 16-28).

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In regard to Claim 11 and 14-20, as discussed previously, Leet et al. disclose a sampling device for collection of cervical tissue/cells. It has been held that the prior art inherently performs a claimed method when that prior art meets the structural limitations of the article of the claimed invention and is used in normal and usual operation (see MPEP 8 2112.02). It is considered normal and usual operation to insert a collection device comprising a tube and a brush into the vagina, extending the stick (if needed) so that the brush is in contact with the cervix, rotating the stick/brush against the cervix, retracting the stick so as return it to the tube of the device, removing the device from the vagina, extending the stick again to re-expose the brush, transferring the cervical cells from the brush onto a glass slide or similar material, and sending the slide for analysis. (Also see Leet et al., column 2, lines 64-36.)

22. Claims 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leet et al. in view of Wallach (US 6,387,058).

In regard to Claim 3, Leet et al. disclose the claimed invention except for the tube 11 being closed by a thin plastic membrane. Wallach discloses an apparatus for self-sampling of a cervical cells comprising a cylindrical plastic tube 30 and a cylindrical plastic stick 14 (abstract; column 3, line 53-column 4, line 35; column 5, line 60-column 6, line 36). Wallach further discloses that the apparatus has a thin plastic membrane (the end portion of tube 30 comprising slots 32). Wallach teaches that the membrane permits easy insertion into the vaginal cavity and assists in locating the device near the cervix (column 5, line 60-column 6, line 11). One would have been motivated to modify the apparatus of Leet et al. to provide for a thin plastic membrane, as taught by

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Wallach, since doing so would permit easy insertion into the vaginal cavity and assist in locating the device near the cervix. Thus, it would have been obvious to one of ordinary skill in the art to modify the apparatus of Leet et al. to provide for a thin plastic membrane, as taught by Wallach, since doing so would permit easy insertion into the vaginal cavity and assist in locating the device near the cervix.

Allowable Subject Matter

23. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record failed to teach or fairly suggest a cervical sampling device comprising a thin plastic membrane located at a particular position within the interior a tubular portion of the device, said membrane being thinner in its central portion.

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Conclusion

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Wallach (US 6,740,049), Abele et al. (US 4,235,244), Ramus (US 903,107), Richards et al. (US 4,657,869), and Alter (US 4,457,313 and US 4,586,604).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keshia Gibson whose telephone number is (571) 272-7136. The examiner can normally be reached on M-F 8:30 a.m. - 6 p.m., out every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Keshia Gibson
Examiner, Art Unit 3761
klg 8/2/05

TATYANA ZALUKAEVA
PRIMARY EXAMINER

